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## REMARKS

Applicants have studied the Office Action mailed July 25, 2006 and have made amendments to the claims. It is respectfully submitted that the application, as amended, is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and following remarks is respectfully requested.

**Rejection of claims 3, 24, and 31-32 under 35 USC §102(b):**

The Examiner reiterated the rejection of claims 3, 24, and 31-32 under 35 USC §102(b) as being anticipated by Miernyk et al. In making this rejection, the Examiner reiterates that Miernyk et al. teaches a polyclonal antibody to a 14 amino acid fragment of pyruvate dehydrogenase, which is the same as amino acids 296-310 of SEQ ID NO:2 in the instant application. The Examiner asserts that, therefore, the antibody taught by Miernyk et al. would inherently bind SEQ ID NO:2.

In response, Applicants respectfully assert that Miernyk et al. does not anticipate any of claims 3, 24, and 31-32.

First, the antibody taught by Miernyk et al. is a polyclonal antibody, whereas claims 3, 24, and 31-32, as hereby amended, are directed to monoclonal antibodies.

Second, Miernyk et al. disclose a polyclonal antibody to a short 14 amino acid-long peptide. In contrast, SEQ ID NO:2 of the instant application is 397 amino acids in length. Thus, instant SEQ ID NO:2 is about 28 times longer than the peptide of Miernyk. A skilled artisan in the antibody field would recognize that a 14 amino acid-long peptide and a 397 amino acid-long protein would be expected to differ significantly in their tertiary structures (three-dimensional shapes), and that such differences in protein tertiary structures would affect antibody binding such as by, for example, preventing access of an antibody to particular epitopes. Due to the expected differences in antibody binding characteristics caused by the extensive three-dimensional structural differences expected to be present in proteins that differ by about 28 orders of magnitude in length, there is a reasonable likelihood that the antibody of Miernyk would not inherently bind to instant SEQ ID NO:2. Certainly, the antibody of Miernyk will not necessarily bind to instant SEQ ID NO:2, as is required for inherent anticipation. Thus, a 102(b)

rejection based on inherent binding of the antibody of Miernyk to instant SEQ ID NO:2 is improper.

Accordingly, Applicants respectfully request that the rejection of claims 3, 24, and 31-32 under 35 USC §102(b) be reconsidered and withdrawn.

**Rejection of claims 3 and 24-36 under 35 USC §103(a):**

The Examiner reiterated the rejection of claims 3 and 24-36 under 35 USC §103(a) as being unpatentable over Miernyk et al. in view of Harlow et al., essentially for the reasons of record put forth in the prior Office Action and in the Examiner's rejection of claims 3, 24, and 31-32 under 35 USC §102(b).

However, in light of the discussion above in regards to the rejection under 35 USC §102(b) in view of Miernyk et al., it is clear that Miernyk et al., even in combination with Harlow et al., neither anticipates nor makes obvious any of claims 3 and 24-36 due at least to the expected differences in the tertiary structures (three-dimensional shapes) of the protein of instant SEQ ID NO:2 and the 14 amino acid-long peptide of Miernyk et al. This obviates the teachings of Harlow et al. with respect to Miernyk et al. as it applies to claims 3 and 24-36 under 35 USC §103(a).

Accordingly, Applicants respectfully request that these rejections under 35 USC §103(a) be reconsidered and withdrawn.

### Conclusions

Claims 3 and 24 are hereby amended, and claims 25-26, 29-30, and 33-34 are hereby canceled. Entry of these amendments is respectfully requested. As such, claims 3, 24, 27-28, 31-32, and 35-36 remain pending and under consideration.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,  
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